

REMARKS

Claims 1-15, 20 and 21 are now pending. By the Office Action, claims 1-12, 16 and 17 are rejected; claims 18 and 19 are withdrawn from consideration; and claims 13-15, 20 and 21 are allowed. By this Amendment, claims 16-19 are canceled and claims 2, 8 and 12 are amended. No new matter is added.

The attached Appendix includes marked-up copies of each rewritten claim (37 C.F.R. §1.121(c)(1)(ii)).

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Schnizer in the November 12 personal interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

I. ALLOWABLE CLAIMS

Applicants appreciate the indication in the Office Action that claims 13-15, 20 and 21 are allowable. Claim 12 was not rejected over prior art. Applicants gratefully acknowledge the indication in the Office Action and in the November 12 personal interview of allowability of claim 12 subject to the §112, second paragraph, rejection being overcome.

II. WITHDRAWN CLAIMS

By this Amendment, claims 18 and 19 are canceled.

III. SECTION 112 REJECTIONS

Claims 1, 2, 8, 12 and 16 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

By this Amendment, claim 16 is canceled, thus rendering the rejection of this claim moot. In addition, claims 2, 8 and 12 are amended as suggested by the Office Action, in order to clarify the claimed flexible range boundaries. The amendments are not narrowing amendments.

For at least these reasons, and as agreed in the interview, amended claims 2, 8 and 12 satisfy the requirements of §112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. SECTION 101 REJECTIONS

Claims 16 and 17 are rejected under 35 U.S.C. §101. By this Amendment, claims 16 and 17 are canceled, thus rendering the rejection of these claims moot. Reconsideration and withdrawal of the rejection are respectfully requested.

V. SECTION 102 REJECTIONS

Claims 1-11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,013,566 to Woodle et al. (Woodle). Applicants respectfully traverse the rejection.

Claim 1 is directed to a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of coagulation factor VIII (FVIII) and substantially neutral colloidal particles, said particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, said polymer carrying substantially no net charge, wherein said FVIII is not encapsulated in said colloidal particles. As agreed in the interview, Woodle does not teach a pharmaceutical composition in which FVIII is not encapsulated in colloidal particles. Instead, Woodle only teaches compounds such as FVIII encapsulated in a liposome. Column 12, lines 7-20.

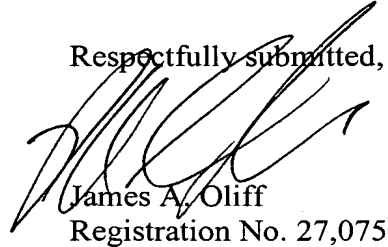
Claims 2-11 depend from claim 1, and thus include all of its limitations. Accordingly, these dependent claims are not anticipated by Woodle for at least the same reasons as claim 1. Reconsideration and withdrawal of the rejection are respectfully requested.

VI. CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance. Prompt allowance of claims 1-15, 20 and 21 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



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Attachment:
Appendix

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<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>
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APPENDIX

Changes to Claims:

Claims 16-19 are canceled.

The following are marked-up versions of the amended claims:

2. (Amended) The pharmaceutical composition of Claim 1 wherein the colloidal particle has a mean particle diameter of ~~between~~ about 0.05 to about 0.4 microns.

8. (Amended) The pharmaceutical composition of Claim 7 wherein the polyethylene glycol has a molecular weight of ~~between~~ about 1000 to about 5000 daltons.

12. (Amended) The pharmaceutical composition of Claim 1 wherein the particle to FVIII ratio (w/unit FVIII) is ~~between~~ about 0.1 mg/unit ~~and to~~ about 10 mg/unit.